REMARKS

Claims 1-30 are pending. Claims 1, 12, and 23 have been amended. No new matter has been entered. Claims 1-30 remain in the application.

The specification and drawings have been amended to correct reference numerals. Replacement drawings, consisting of twenty-eight (28) sheets, and annotated drawings of FIGURE 1 and FIGURE 13A are included with this paper. No new matter has been entered.

Claims 1, 5-12, 14-23, and 25-30 stand rejected under 35 U.S.C. § 102(e); however, U.S. Patent No. 6,306,088, issued to Krausman et al. ("Krausman") has been applied against Claims 1-11, 14-23, and 25-30 under the 35 U.S.C. § 102(e) rejection. Additionally, Claim 2 is separately rejected as obvious under 35 U.S.C. § 103(a). Consequently, for purposes of response, the 35 U.S.C. § 102(e) rejection is assumed to apply to Claims 1, 3-12, 14-23, and 25-30, and the 35 U.S.C. § 103(a) rejection is assumed to apply to Claims 2, 13, and 24. Clarification or confirmation are requested.

Claims 1, 3-12, 14-23, and 25-30 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Krausman. A claim is anticipated under 35 U.S.C. § 102(e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. Applicant traverses the rejection.

Krausman discloses a method and apparatus for aiding in diagnosing a medical condition of a fully ambulatory subject using self-contained recording units, which include physiological parameter sensors, a programmable controller with embedded programmable read only memory, and an analog to digital converter (Col. 4, lines 26-59). The recording units are placed on a patient at multiple measurement sites for providing output data measured by the sensors. The data is measured at prescribed time intervals (Col. 4, lines 36-50) over a specified time period, such as a full night of sleep or other extended period of time (Col. 5, line 66-Col. 6, line 2). The sensor output data is time stamped and stored by the recording unit until the data is transferred via a smart input and output interface device to an external computer (Col. 4, lines 50-55). The external

computer uses application software to analyze and display temporal variations in the data for aiding in diagnosing the medical condition of the patient (Col. 4, lines 56-59).

Independent Claims 1, 12, and 23 have been amended to recite testing the patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a pathophysiology indicative of at least one of an onset, progression, regression, and status quo of respiratory insufficiency. Support for the claim amendments can be found in the specification on page 20, lines 6-13; page 21, lines 24-29; page 28, lines 13-24; page 29, lines 3-20; and page 33, lines 1-21. Hence, no new matter has been entered.

Such limitations are neither taught nor suggested by the Krausman reference. Claims 1, 12, and 23 recite an indicator threshold corresponding to a pathophysiology indicative *of at least one of* an onset, progression, regression, *and* status quo of respiratory insufficiency (emphases added). *See, e.g.*, Spec., page 20, lines 6-13. In contrast, Krausman teaches aiding in diagnosing a patient medical condition using a threshold for determining the presence of medical condition indicators, such as sleep disorder breathing events (DBE) (Col. 9, lines 51-62; Col. 10, lines 1-11). A detection algorithm requires finding maximum and minimum sensor levels during a specified time period (Col. 10, lines 1-4). A central DBE is determined to begin when a "max-min" point falls below a specified threshold and end when the "max-min" point rises above the same threshold (Col. 10, lines 6-11).

Krausman teaches <u>detecting</u> the presence of a medical condition, rather than diagnosing a medical condition, such as respiratory insufficiency <u>and</u> monitoring that medical condition. In contrast, Claims 1, 12, and 23 recite testing for <u>four</u> possible outcomes: onset, progression, regression, and status quo, any of which outcome can potentially be determined. If a finding of respiratory insufficiency has not previously been diagnosed, a determination of respiratory insufficiency onset is possible (Spec., p. 29, lines 4-6). If respiratory insufficiency was previously diagnosed, a determination of respiratory insufficiency

progression or regression is possible (Spec., p. 29, lines 7-10). Moreover, if no change is detected, a determination of status quo is possible (Spec., p. 29, lines 10-13). In contrast, the detection algorithms in Krausman determine whether a DBE is either present or absent, and afford no further diagnosis. Determining the presence of a medical condition is different than determining one of four possible respiratory insufficiency diagnoses. Therefore, Krausman fails to teach or suggest determining at least one of an onset, progression, regression, and status quo of respiratory insufficiency, per Claims 1, 12, and 23.

Additionally, Krausman teaches an external medical sensor for an ambulatory patient that samples sensor output data during prescribed time intervals (Col. 4, lines 49-50), such as during a full night's sleep or over other extended periods (Col. 5, line 66-Col. 6, line 2). Output data is only collected during the prescribed time intervals when the patient is physically wearing the external recording unit. Krausman thus focuses on acute indicators, such as airflow and respiration effort, of an underlying medical condition, rather than diagnosing or detecting *chronic* indicators of a medical condition. Claims 1, 12, and 23, by comparison, recite measures that are recorded on a substantially continuous basis *See, e.g.*, Spec., page 11, lines 27-30. Chronic medical conditions are often difficult to detect when a patient is monitored intermittently during specific prescribed time intervals since a chronic condition usually exhibits symptoms gradually over a period of time. The continuous recordation of measures recited by Claims 1, 12, and 23 enables detection of either acute or chronic medical condition indications in further distinction from Krausman.

Accordingly, Krausman fails to anticipate independent Claims 1, 12, and 23. Claims 3-11 are dependent upon Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations therein. Claims 14-22 are dependent upon Claim 12 and are patentable for the above-stated reasons, and as further distinguished by the limitations therein. Claims 25-30 are dependent upon Claim 23 and are patentable for the above-stated reasons, and as further distinguished by the limitations therein. Withdrawal of the rejection is respectfully requested.

Claims 2, 13, and 24 stand rejected under 35 U.S.C. § 103(a) as being obvious over Krausman, as applied to Claims 1, 12, and 23 above, and further in view of U.S. Patent No. 5,704,345, issued to Berthon-Jones. Applicant traverses the rejection.

Claim 2 is dependent upon Claim 1 and is patentable for the above-stated reasons, and as further distinguished by the limitations therein. Claim 13 is dependent upon Claim 12 and is patentable for the above-stated reasons, and as further distinguished by the limitations therein. Claim 24 is dependent upon Claim 23 and is patentable for the above-stated reasons, and as further distinguished by the limitations therein. Withdrawal of the rejection is respectfully requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

Claims 1-30 are believed to be in a condition for allowance. Entry of the specification, drawing, and claim amendments, and further examination are respectfully requested. A Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

Respectfully submitted,

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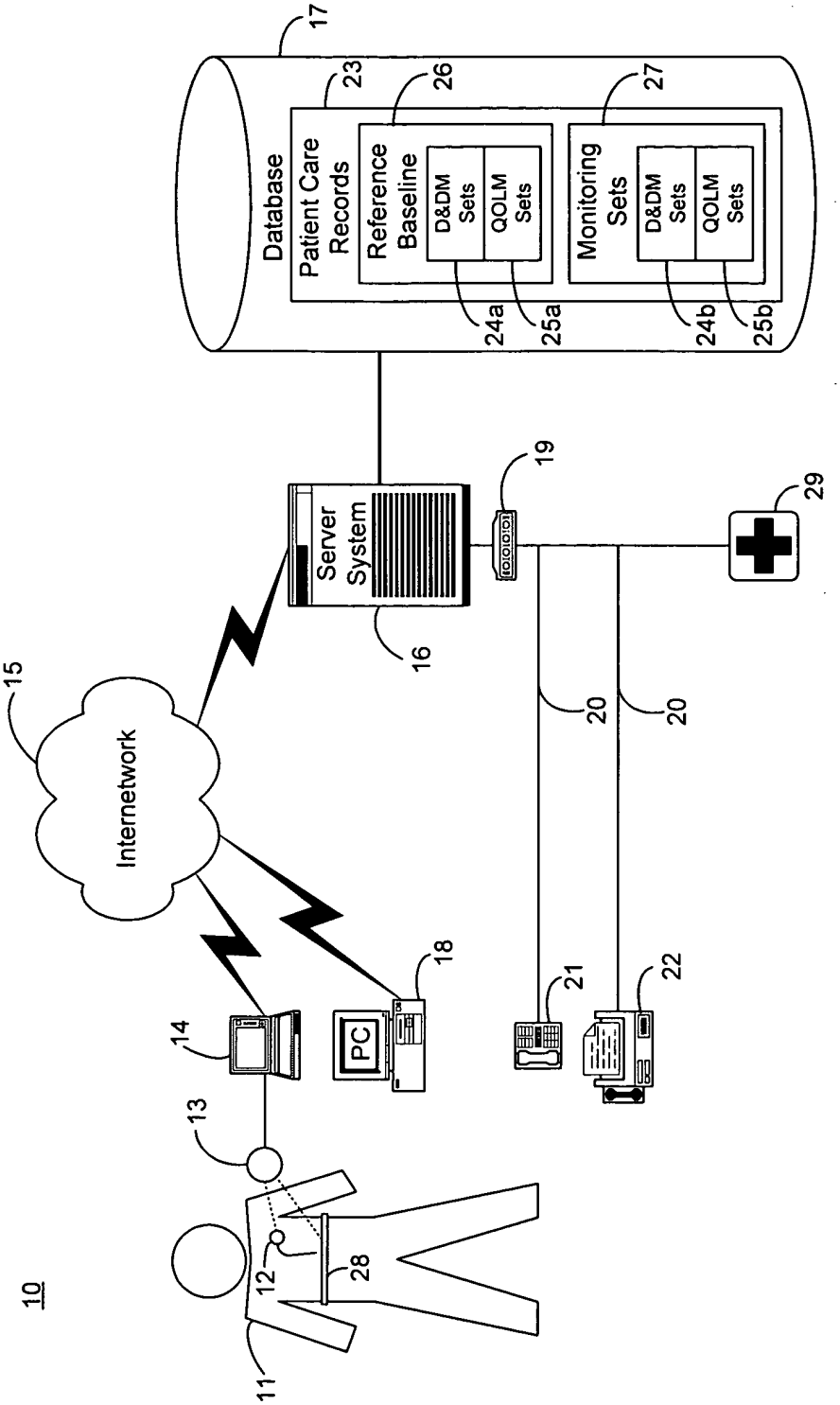

Figure 1.

Figure 13A.